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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MITRA, RITA

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 10/07/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary

Application No.

09/687,276

Applicant(s)

PRAYAGA ET AL.

Examiner

Rita Mitra

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-48 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, 33, 36, drawn to an isolated polypeptide comprising an amino acid sequence consisting of a mature form of amino acid of SEQ ID NO: 2, 5 and 7; variants, composition and kit comprising the said polypeptide; classified in class 530, subclass 350.
- II. Claims 5-14, 34, 37 drawn to an isolated nucleic acid molecule comprising a nucleic acid sequence related to SEQ ID NO: 1, 4 and 6 encoding a polypeptide comprising an amino acid sequence consisting of a mature form of amino acid of SEQ ID NO: 2, 5 and 7; variants, fragments, a complement of SEQ ID NO: 1, 4 and 6, vector, host cells, composition and kit comprising the said nucleic acid; classified in class 435, subclass 69.1; class 536, subclass 23.5.
- III. Claims 15-17, 35, 38, drawn to an antibody specific for polypeptide of claim 1, composition and kit comprising the said antibody; classified in class 530, subclass 387.1+.
- IV. Claim 18, drawn to a method of detecting polypeptide of claim 1 using antibody; classified in class 435, subclass 7.1.
- V. Claims 19-22, drawn to a method of detecting nucleic acid of claim 5 using nucleic acid probe; classified in class 536, subclass 23.1, 24.3; class 435, subclass 6.
- VI. Claims 23 and 24, drawn to a method for the identification of an agent that binds to a polypeptide, wherein the polypeptide comprises SEQ ID NO: 2 and variants thereof, and the agent is a compound that can modulate actin polymerization classified in class 435, subclass 7.1.

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- VII. Claim 25, drawn to a method for the identification of an agent that modulates the expression of the polypeptide of SEQ ID NO: 2 or 5 or 7, comprising providing a cell expressing said polypeptide, classified in class 435, subclass 7.95, class 435, subclass 471.
- VIII. Claim 26, drawn to a method for modulating the activity of the polypeptide comprising SEQ ID NOs: 2 or 5 or 7, classified in class 514, subclass 1.
- IX. Claims 27, 28 and 39, drawn to a method of treating or preventing a NOV-associated disorder, comprising administering to a subject the polypeptide of SEQ ID NO: 2 or 5 or 7, classified in class 514, subclass, 2.

Should a Group IX be elected, applicants are required to select either NOV polypeptide or NOV nucleic acid or NOV antibody from claim 39.

- X. Claims 29 and 30, drawn to a method of treating or preventing a NOV-associated disorder, comprising administering to a subject the nucleic acid encoding a polypeptide of SEQ ID NO: 2 or 5 or 7, classified in class 514, subclass, 44.
- XI. Claims 31 and 32, drawn to a method of treating or preventing a NOV-associated disorder, comprising administering to a subject the antibody that binds to the protein of SEQ ID NO: 2 or 5 or 7, classified in class 424, subclass, 130.1.
- XII. Claims 40 and 41, drawn to a method for screening for a modulator of activity comprising administering a test compound to a test animal, wherein said test animal recombinantly expresses the polypeptide of SEQ ID NO: 2 or 5 or 7. classified in class 800, subclass, 3.
- XIII. Claim 42, drawn to a method for determining the presence of or predisposition to a disease associated with altered levels of the polypeptide of SEQ ID NO: 2 or 5 or 7. in a first mammalian subject. classified in class 435, subclass, 7.1.
- XIV. Claim 43-46, drawn to a method for determining the presence of or predisposition to a disease associated with altered levels of nucleic acid molecule encoding a polypeptide of SEQ ID NO: 2 or 5 or 7, classified in class 435, subclass, 6.

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- XV. Claim 47, drawn to a method of treating a pathological state in a mammal, comprising administering to the mammal a polypeptide, wherein the polypeptide having an amino acid sequence at least 95% identical to a polypeptide of SEQ ID NO: 2 or 5 or 7 or a fragment thereof, classified in class 514, subclass, 2.
- XVI. Claim 48, drawn to a method of treating a pathological state in a mammal, comprising administering to the mammal an antibody that specifically binds to the polypeptide of SEQ ID NO: 2 or 5 or 7, classified in class 424, subclass, 130.1.

Should a Group from Groups I, IV, VI-IX, XII, XIII and XV be elected, applicants are required to select one sequence from SEQ ID NO: 2, 5 and 7.

Should a Group from Groups II, V, X, XIV and XVI be elected, applicants are required to select one sequence from SEQ ID NO: 1, 4 and 6.

The inventions are distinct, each from the other because of the following reasons:

The polypeptide of group I and nucleic acid of group II is related to by virtue of the fact that the DNA codes for the protein. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA and the protein are related, since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by other and materially distinct processes, such as purification from the natural source. Further, DNA can be used for processes other than the production of protein, such as nucleic acid hybridization assays. Therefore, the inventions are distinct.

The polypeptide of group I is related to the antibody of group III by virtue of being the cognate antigen necessary for the production of antibody. Although the protein and antibody are related due to the necessary steric complementarity of the two, they are distinct inventions because the protein can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein if it is a receptor. Further, a protein and its cognate

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antibody are structurally and functionally distinct molecules with different amino acid compositions. Therefore, the inventions are distinct.

Inventions I and IV, VI, VII, VIII, IX, XII, XIII, XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown:

(1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the claimed polypeptide of I can be used in a materially different process such as for the production of antibody specific for the polypeptide. Therefore, the inventions are distinct.

Inventions I and V, X, XI, XIV, XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptide of group I is not necessary for the practice of claimed method of groups V, X, XI, XIV and XVI. Therefore the inventions are distinct.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acid of group II is a separate and distinct chemical entity from antibody of group III. The nucleic acid has different functions from the antibody of III and is not necessary for the practice of the claimed method. Therefore the inventions are distinct.

Inventions II and V, X, XIV and XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the claimed nucleic acid of II can be used in a materially different process such as for the production of protein by recombinant method. Therefore, the inventions are distinct.

Inventions II and IV, VI, VII, VIII, IX, XI, XII, XIII, XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

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different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acid of group II is not necessary for the practice of claimed method of group IV, VI, VII, VIII, IX, XI, XII, XIII, XV. Therefore the inventions are distinct.

Inventions III and IV-X, XII-XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibody of group III is not necessary for the practice of claimed method of group IV-X, XII-XVI. Therefore the inventions are distinct.

Inventions III and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the claimed antibody of III can be used in a materially different process such as for the purification of protein by affinity chromatography. Therefore, the inventions are distinct.

Inventions IV and V, X, XIV, XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptide detection method of group IV and methods of groups V, X, XI, XIV, XVI are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. Therefore the inventions are distinct.

Each of inventions V, X, XIV, XVI are related by virtue of the nucleic acid, which is used in the methods. The inventions are distinct, however, each from the other, because they are directed to different mode of operations and different outcomes. Therefore, the inventions are distinct

Inventions V and IV, VI, VII, VIII, IX, XI, XII, XIII, XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP

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§ 808.01). In the instant case the nucleic acid detection method of group V and methods of groups IV, VI, VII, VIII, IX, XI, XII, XIII, XV are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. Therefore the inventions are distinct.

Each of inventions IV, VI, VII, VIII, IX, XII, XIII, XV are related by virtue of the polypeptide, which is used in the methods. The inventions are distinct, however, each from the other, because they are directed to different outcomes and the identification of compounds having separable and materially distinct activities and different functions. Therefore, the inventions are distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

A telephone call was made to Attorney Ivor Elrifi on July 8, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The


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Examiner can normally be reached from 10:00 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Rita Mitra, Ph.D.

October 1, 2002


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